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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,868	02/26/2002	Gregg S. Sutton	CRD-0991	1377

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/083,868	Applicant(s) SUTTON ET AL.	
	Examiner Michael Thaler	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/17/02, 11/18/03</u> . | 6) <input type="checkbox"/> Other: ____ |

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The disclosure is objected to because of the following informalities: On page 14, line 5, "376" should be "375". Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, lines 15-17 (of the page), it is unclear if "variable" means that 1) each of the openings can have a diameter within the given range (This includes the possibility that all of the openings have the same diameter in a particular filter membrane.) or 2) the diameters of the openings vary in a particular filter membrane. In claim 8, although it can be seen how fibers can be attached to other fibers or other members, it is not seen how the fibers can be attached to the openings (the open spaces).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaganov et al. (5,876,367). Kaganov et al., in figure 2, disclose housing 10 having a proximal end (the right end) comprising a connector (the proximal balloon 35 shown in figure 6 and which is disclosed as being included in the figure 2 embodiment in col. 10, lines 40-44) adapted to connect to a hose (i.e. the blood vessel. Alternatively, balloon 35 is inherently capable of being connected to a man-made hose either inside or outside the blood vessel. The hose could be outside the blood vessel since the proximal ends of both tubular members 10 and 14 could be located outside the blood vessel while the distal end of the shunt is inside the blood vessel) and a distal end comprising a distal member (the left branch of housing 10) having two openings 13, 18, wherein the housing comprises a

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first lumen 11 and a second lumen 15 extending from a port 16 to an opening 18 and vascular filter system 41, 42 comprising a filter membrane support structure (e.g. the umbrella frame described in col. 9, lines 64-67) and a filter membrane having openings of diameters which are "variable", as best understood, depending on the pore size which is chosen for the particular filter as described in col. 9, lines 7-37. The Kaganov et al. system is inherently capable of being used as a cardiopulmonary bypass filter system. As to claim 2, the Kaganov et al. system is inherently capable of being connected to a cardiopulmonary bypass machine by for example, connecting the right end of tube 10 to it via a hose. As to claims 3 and 4, Kaganov et al. disclose distal flange (the distal balloon 35 shown in figure 6 and which is disclosed as being included in the figure 2 embodiment in col. 10, lines 40-44). As to claim 8, as best understood, Kaganov et al. disclose fibers (the threads which make up the filter, noting the term "thread" in col. 8, line 1 and that threads, by definition, include fibers).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaganov et al. (5,876,367). Kaganov et al. fail to disclose the openings being non-uniformly spaced. However, it is old and well known in this art to so space filter openings in order to optimize the filtering process. It would

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have been obvious to make the openings of the Kaganov et al. filter non-uniformly spaced so that it too would have this advantage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
6/7/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731